

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HOLOGIC, INC., and CYTYC SURGICAL
PRODUCTS, LLC,

Plaintiffs,

vs.

MINERVA SURGICAL, INC.,

Defendant.

1:15-cv-1031

MEMORANDUM AND ORDER

This matter is before the court on the parties' motions in limine (D.I. 383, D.I. 384, D.I. 385, D.I. 386, D.I. 387, D.I. 388, D.I. 392, D.I. 393, D.I. 394, D.I. 395, D.I. 396, and D.I. 397).

Although the motion in limine is an important tool available to the trial judge to ensure the expeditious and evenhanded management of the trial proceedings, performing a gatekeeping function and sharpening the focus for later trial proceedings, some evidentiary submissions cannot be evaluated accurately or sufficiently by the trial judge in such a procedural environment. [*Jonasson v. Lutheran Child and Family Servs.*, 115 F.3d 436, 440 \(7th Cir. 1997\)](#). A motion in limine is appropriate for "evidentiary submissions that clearly ought not be presented to the jury because they clearly would be inadmissible for any purpose." *Id.* In other instances, it is necessary to defer ruling until during trial, when the trial judge can better estimate the impact of the evidence on the jury. *Id.* The Eighth Circuit has noted that "[e]videntiary rulings made by a trial court during motions in limine are preliminary and may change depending on

what actually happens at trial.” *Walzer v. St. Joseph State Hosp.*, 231 F.3d 1108, 1113 (8th Cir. 2000). Evidentiary rulings, especially ones that encompass broad classes of evidence, should generally be deferred until trial to allow for the resolution of questions of foundation, relevancy, and potential prejudice in proper context. See *Leonard v. Stemtech Health Scis., Inc.*, 981 F. Supp. 2d 273, 276 (D. Del. 2013).

To the extent that a party challenges the probative value of the evidence, an attack upon the probative sufficiency of evidence relates not to admissibility but to the weight of the evidence and is a matter for the trier of fact to resolve. *United States v. Beasley*, 102 F.3d 1440, 1451 (8th Cir. 1996).

The court is unable to evaluate the relevance of much of the challenged evidence in the context of a pretrial motion. The parties’ concerns may warrant a cautionary or limiting instruction, but the court cannot determine the scope of such an instruction at this time. The court will admit the challenged evidence only on a showing that it is relevant to the remaining issues in the case, and only to the extent that the relevance of the evidence outweighs its potential to cause prejudice or confusion under *Fed. R. Evid.* 403.

With those principles in mind, the court finds as follows.

I. Minerva’s Motions

A. Minerva’s Motion in Limine No. 1: to Exclude Improper Willfulness Evidence (D.I. 383)

Minerva moves to exclude the following improper evidence relating to Hologic’s claim of willful infringement: (1) FDA equivalence documents and testimony; (2) unfounded third-party statements; and (3) any reference to lack of opinion of counsel.

Minerva argues Hologic should be precluded from using any documents or testimony relating to any communications between the FDA and Minerva comparing Minerva's Endometrial Ablation System ("EAS") to Hologic's NovaSure in order to get FDA approval. In particular, it seeks exclusion of PTX-0041 (D.I. 293-2, Ex. 65), an email between the FDA and Minerva in July of 2010 wherein Minerva's employee stated: "The Minerva device is almost dead identical to NovaSure except using plasma energy (RF)." It argues the statement was made in the context of getting FDA approval for a clinical study and had nothing to do with the manufacturing or design of Minerva's infringing product. It contends the probative value of the evidence outweighs the potential for prejudice.

The court cannot determine the admissibility of any ostensible evidence on "FDA equivalence" in a pretrial motion. To the extent it relates to infringement or invalidity issues it has been rendered moot. It may be relevant to willfulness, depending on the circumstances. Minerva's motion seems to go to the weight rather than the admissibility of the evidence.

Minerva next contends Hologic should be precluded from using any third-party statements where no live witness or deposition testimony can provide proper foundation. Particularly, it challenges the admissibility of PTX-0058 (D.I. 293-4 at Ex. 83), a third party (Dr. Ted L. Anderson) email communication dated January 27, 2011 to Minerva's employee (Michael Regan). Dr. Anderson was never deposed and is not on the witness list and the recipient of the email stated at his deposition that he did not recognize it. Minerva contends Hologic has no way of laying a proper foundation to introduce the email.

The court finds a blanket prohibition is not warranted. The court is unable to rule on the admissibility of the challenged evidence in a pretrial motion. The proponent of the evidence will have to establish foundation and overcome any hearsay objections. Evidence will be admitted only on a proper showing of foundation and only if the probative value of the evidence outweighs its potential for prejudice or confusion.

Minerva also seeks preclusion of “any reference to lack of opinion of counsel” under 35 U.S.C § 298. That statute provides:

The failure of an infringer to obtain the advice of counsel with respect to any allegedly infringed patent, or the failure of the infringer to present such advice to the court or jury, may not be used to prove that the accused infringer willfully infringed the patent or that the infringer intended to induce infringement of the patent.

[35 U.S.C. § 298](#). The protection granted by [35 U.S.C. § 298](#) dissolves in the event defendants “open the door” by attempting to refute a claim of willful infringement by implying that they relied on the advice of counsel.

Again, the court is unable to evaluate the issue in this context. The issue depends on the evidence at trial. Minerva produced an opinion of counsel and has its opinion counsel, Mr. Burt Magen, on its witness list. Accordingly, the court finds Minerva’s motion should be denied without prejudice to timely reassertion at trial, should the issue arise.

B. Minerva’s Motion in Limine No. 2: to Exclude Improper Mental State Opinions and Copying Evidence (D.I. 384)

Minerva seeks to exclude testimony by Hologic’s technical expert, Mr. Karl Leinsing, characterizing his testimony as providing “opinions directed to mental state.” (D.I. 384 at 1).

In response, Hologic contends Minerva raised the same flawed arguments in its *Daubert* motion (D.I. 280 at 6), which the court denied after finding Minerva's position "misplaced." (D.I. 407 at 16). A relevant consideration of whether Minerva willfully infringed is whether it copied the claimed invention. While it is the fact-finder's province to draw inferences on issues of intent, the facts demonstrating copying are buried in Minerva's laboratory notebooks, core technical documents, and FDA submissions, the significance of which would not be apparent to a lay juror lacking Mr. Leinsing's technical expertise. Again, testimony that invades the province of the jury will not be allowed, but testimony that merely assists the trier of fact will be allowed. An expert's testimony will, of course, be subject to a showing of proper foundation and reliability.

Again, the court finds the motion should be denied without prejudice to reassertion. The court cannot determine the relevance of the challenged testimony at this time.

To the extent the testimony relates to issues of infringement, the jury will be instructed that Minerva infringes the patents in suit as a matter of law. The challenged evidence may also be relevant to unfair competition and deceptive trade practices claims, but the court cannot make that determination at this time.

C. Minerva's Motion in Limine No. 3: to Exclude Improper Opinions Regarding Legal Issues (D.I. 385)

Minerva seeks to preclude Hologic's technical expert, Karl Leinsing ("Leinsing"), from offering the following improper testimony regarding legal issues: (1) explanation of the law regarding infringement by a separately-patented accused product; (2) legal analysis and explanation of the law regarding joint infringement; and (3) testimony that

Minerva prevented Hologic from inspecting Minerva's accused Endometrial Ablation System ("Minerva's EAS").

In response, Hologic states that it does not intend to offer Dr. Leinsing's testimony affirmatively. The court finds Minerva's motion generally relates to evidence regarding infringement and invalidity, and therefore has been rendered moot by the court's ruling on the parties' summary judgment motions.

Generally, the court will not allow testimony on matters of law that invade the province of the court. That said, some of the proffered evidence may be admissible, depending on the evidence, to refute other evidence. To the extent that any challenged evidence remains relevant, admissibility is dependent on how the evidence unfolds at trial. Accordingly, the court finds that the motion in limine should be overruled at this time, without prejudice to its reassertion via timely objection to the admissibility of such evidence at trial.

D. Minerva's Motion in Limine No. 4: to Exclude Ipse Dixit DOE Opinions for the '348 Patent (D.I. 386)

The court finds the motion has been rendered moot by the court's finding that Minerva directly infringes the '348 Patent as a matter of law. Accordingly, the motion in limine will be denied.

E. Minerva's Motion in Limine No. 5: to Exclude Inadmissible Hearsay Testimony (D.I. 387)

Minerva essentially makes a blanket request for exclusion of hearsay evidence. This is the sort of evidentiary ruling that is more properly the subject of a timely objection at trial. The court finds the motion should be denied without prejudice to reassertion. The court intends to follow the Federal Rules of Evidence regarding

hearsay. Admissibility may be dependent on the purpose for which the testimony is offered (such as the effect on the listener, knowledge, or state of mind), whether the evidence is an admission of a party opponent, or whether the proffered evidence qualifies under the business records or other exception to the hearsay rule. Any concerns of prejudice may be obviated by the procedure set out in the parties' Joint Pretrial Order (D.I. 367), wherein the parties have agreed to meet and confer regarding any objections to deposition designations and exhibits and submit the issue to the court the night before the deposition testimony or exhibits are to be introduced. The parties should approach the bench or otherwise take up any contentious issues outside the presence of the jury.

F. Minerva's Motion in Limine No. 6: to Exclude Evidence and Argument Concerning Price Erosion (D.I. 388)

Minerva contends that, after initially asserting price erosion to support its preliminary injunction motion, Hologic expressly disclaimed that theory. Minerva argues that Hologic's witnesses have admitted pricing for NovaSure increased and its damages expert disclaims a price erosion theory of damages. Minerva thus challenges the foundation for any such evidence. It contends evidence of price erosion is irrelevant and, if relevant, is unduly prejudicial and confusing and will result in unnecessary delay.

In response, Hologic contends the category of evidence Minerva seeks to exclude is relevant. For example, Hologic argues the evidence on Minerva's effect on pricing shows that the parties' products directly competed with each other for the same customers in the same market, which relates to both lost profits and reasonable royalty.

Minerva's concerns may go more to the weight than admissibility of the evidence and can be handled in cross-examination or in a cautionary instruction. The court

cannot make a determination at this time and the motion will be denied without prejudice to reassertion.

II. Hologic's Motions:

A. Hologic's Motion in Limine No. 1: to Exclude Reference to or Use of Inter Partes Review Proceedings Relating to the '183 Patent-in-Suit (D.I. 392)

Hologic requests an order in limine precluding Minerva from referring to or using at trial the Inter Partes Review proceeding regarding U.S. Patent No. 6,872,183 ("the '183 Patent") in the Patent Trial and Appeal Board ("PTAB") case number IPR2016-00868, including the Patent Office's decision in that proceeding that is pending appeal before the Federal Circuit. It argues prejudice and confusion outweigh the probative value of any such evidence.

In response, Minerva argues the PTAB's decision is relevant with respect to willfulness because the focus is Minerva's subjective knowledge. Minerva contends the initiation of the proceedings shows Minerva's subjective belief that the patent was invalid. It argues the PTAB decision is objective evidence that corroborates Minerva's subjective belief.

To the extent the motion relates to issues of invalidity or infringement, the motion has been rendered moot by the court's ruling on summary judgment. Generally, the court is inclined to find that because the patent office proceeding and decision are not binding and are on appeal, the prejudicial and confusing effect of the evidence almost certainly outweighs any probative value, at least with respect to the merits. The substance of the proceeding and decision will not be admitted.

To the extent the fact of initiation of the proceeding may be relevant to issues of subjective intent and willfulness, the court's finding on assignor estoppel may preclude Minerva from presenting any argument that the patent is invalid. Though it may not present evidence of the PTAB's findings, the fact that it filed the PTAB action may be relevant to intent or state of mind and Hologic, by moving for enhanced damages, may be said to have waived its right to assert assignor estoppel.

Without knowing the evidence and what it is proffered for, the court cannot make a determination as to the precise parameters of the admission of this evidence, if any. Accordingly, the motion will be granted with respect to the PTAB's substantive proceeding, findings, and decision, but denied without prejudice to reassertion at trial as it relates to intent.

B. Hologic's Motion in Limine No. 2: to Preclude Minerva From Referencing Its Patents and Patent Applications at Trial (D.I. 393)

Hologic requests that the court preclude Minerva from referring at trial to its own patents and patent applications (and prosecution histories) to (1) argue or suggest that Minerva does not infringe; (2) to argue or suggest that its infringement has not been willful; and (3) to argue or suggest that Minerva's product embodies its patents.

The motion is moot with respect to issues other than willfulness. In response, Minerva contends the evidence as it relates to willfulness is relevant to its state of mind and it would be reversible error to exclude it.

The court first finds Hologic's reliance on case-law that pre-dates [*Halo Electronics, Inc. v. Pulse Electronics, Inc.*, 136 S.Ct. 1923 \(2016\)](#) is misplaced. Evidence that relates to intent is admissible on the willfulness issue. [*Exmark Mfg. Co. v. Briggs & Stratton Power Prods.*, 879 F.3d 1332, 1353 \(Fed. Cir. 2018\)](#). Evidence of

some of Minerva's patents are most likely relevant to the issue of intent and will be admitted for that limited purpose of that issue. The evidence may also be relevant to damages under factors set out in *Georgia-Pac. Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), *modified sub nom. Georgia-Pac. Corp. v. U.S. Plywood-Champion Papers, Inc.*, 446 F.2d 295 (2d Cir. 1971), i.e., to show portion of profits credited to the invention as opposed to non-patented elements or improvements added by Minerva. Minerva's patents will not be admitted to show or suggest that the fact that Minerva obtained a patent means they do not infringe Hologic's patent. That issue has been resolved as a matter of law. Also, the court will not permit collateral disputes dealing with the scope and validity of Minerva's patents.

Accordingly, the motion to preclude evidence of patents will be granted as to evidence that relates to infringement or embodiment and denied as to evidence that relates to willfulness or damages.

C. Hologic's Motion in Limine No. 3: to Exclude Minerva's Undisclosed Fact Witness, Akos Toth (D.I. 394)

Hologic moves to preclude Akos Toth from testifying at trial. It argues Toth was not listed as a witness nor identified in initial or supplemental disclosures as an individual with relevant information. It contends it was surprised and will be prejudiced by Minerva's failure to disclose Toth.

Minerva responds that the motion is moot in light of the court's order granting Hologic's motion for summary judgment of infringement. Further, Minerva states that it not only timely disclosed Toth as a rebuttal fact witness pursuant to the court's scheduling order (D.I. 265), but actively sought and obtained documents relating to Toth during discovery and relied on Toth's documents in its expert reports.

The challenged evidence apparently relates to expert reports and lab notebooks that go to validity and infringement issues. The court thus finds the motion should be denied as moot.

D. Hologic's Motion in Limine No. 4: to Preclude Minerva, Its Attorneys, and Experts from Arguing that the Patents-in-Suit do not Enable or Describe Unclaimed Features of the Accused Product (D.I. 395)

This motion relates to invalidity defenses and is moot by reason of the court's summary judgment ruling.

E. Hologic's Motion in Limine No. 5: to Preclude Minerva, Its Attorneys, and Experts from Rearguing or Taking Positions Inconsistent with This Court's Claim Construction (D.I. 396)

Hologic moves to preclude Minerva from adducing evidence on or arguing positions inconsistent with the court's claim construction. Particularly it challenges the testimony of Dr. Robert Tucker, who analyzed the asserted patents' specifications and discussed what a person of ordinary skill in the art would have understood those specifications to teach and seeks to exclude certain testimony from inventor Csaba Truckai (and opinions from Tucker that apply Truckai's testimony) on what he believed were the scope of his inventions.

Minerva concedes that testimony that pertains to Dr. Tucker's opinions on invalidity and infringement are moot in light of the court's summary judgment order. Also, Minerva states that it does not plan to reargue claim construction or take positions inconsistent with the claim construction order. It argues, however, that to the extent Truckai and other Minerva witnesses discuss the specifications of the patents to explain why Minerva reasonably believes it does not infringe, such testimony is directly relevant to the "totality of the circumstances" test for willfulness and speaks to Truckai's state of

mind about what he believed he invented, what he believed the patents' specifications teach, and what he believed the claims cover.

The court finds that evidence relevant to intent and state of mind may be admissible on the issue of willfulness. Accordingly, the court finds the motion should be denied with respect to evidence that relates to willfulness, but granted in all other respects.

F. Hologic's Motion in Limine No. 6: to Preclude Minerva from Relying on Trial Exhibits that Minerva Failed to Produce During Discovery (D.I. 397)

Hologic seeks to preclude Minerva, its attorneys, witnesses and experts from relying on evidence of the individual components of the accused controller (and pictures thereof) that Minerva objected to and did not produce in discovery. It contends that Minerva seeks to introduce as part of its own claims and defenses the components it would not produce. Particularly it objects to admission of (DTX-1372 (Sample: Orifice from Minerva EAS); DTX-1373 (Sample: Airflow sensors from Minerva EAS); DTX-1332: (Pictures of Orifice)). In response, Minerva disputes that it withheld the items, but contends the components were produced as part of Minerva's entire controller.

It appears to the court that this motion may also be moot, though the parties have not argued mootness. The court fails to see the relevance of the challenged evidence to the remaining issues in the litigation. Further, the court cannot assess the relative levels of gamesmanship that may have occurred with respect to this disputed evidence. Accordingly, the motion will be denied at this time without prejudice to reassertion at trial. The evidence will not be admitted absent a showing of proper foundation and relevance. Accordingly,

IT IS ORDERED that the parties' motions in limine (D.I. 383, D.I. 384, D.I. 385, D.I. 386, D.I. 387, D.I. 388, D.I. 392, D.I. 393, D.I. 394, D.I. 395, D.I. 396, and D.I. 397) are granted in part and denied in part as set forth in this order.

DATED this 6th day of July, 2018.

BY THE COURT:

s/ Joseph F. Bataillon
Senior United States District Judge